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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,299	11/11/2003	Assaf Govari	U 014946-4	5768

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LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,299	GOVARI ET AL.	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application is published application number: 2005/0101946.

The effective filing date of this application is 11-11-03.

Pending claims are 1-29. Claims 25-29 are new.

Elected (without traverse) claims 18-29 are examined below. Claim 18 is the lone independent. Non-elected / withdrawn claims are 1-17.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Application neglects to sufficiently describe **in the original disclosure** a capacitor core with a slit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh (6,802,857) in view of Spillman, Jr. et al. (6,206,835).

Walsh is silent regarding a control circuit and physiological sensors.

Independent claim 18 (parentheticals toward Walsh unless stated otherwise)

Walsh discloses a system for electrically isolating a cardiac chamber, comprising: a resonant circuit (18, col. 4:14) having a resonant frequency, said resonant circuit being constructed and dimensional for introduction into an operative position in a pulmonary vein (anticipated by language toward a "vessel" in col. 4:1-3; also note that this is intended use language) of a subject proximate an ostium of said pulmonary vein (intended use langauge);

a catheter (col. 1:44-48) adapted to carry said resonant circuit into said operative position in said pulmonary vein;

a stent (10) dimensioned for circumferential engagement with an inner wall of said pulmonary vein (intended use language; analogues disclosed: artery, passageway, see col. 4:1-3) to define a circumferential region (depicted in figure 8, element 46 is the vessel, the RF field is 36) of contact between said stent (10) and said pulmonary vein (intended use language), wherein a principal axis of said stent is substantially aligned coaxially (depicted in figure 8, element 46 is the vessel, the RF field is 36) with said pulmonary vein, said resonant circuit being

incorporated in said stent (incorporation disclosed at least once, see col. 4:22-24); and

a generator (col. 5:65 through col. 6:6; col. 1:8-10) disposed external to said subject for generating an electromagnetic field that has a frequency substantially equal to said resonant frequency of said resonant circuit, said electromagnetic field operatively including said resonant circuit and causing said resonant circuit to re-radiate electromagnetic energy so as to ablate (col. 5:50-65) intramural target tissue in said pulmonary vein; and

a sensor system (68 **Spillman patent**) to position and orient (as determined by changes in blood pressure once the stent is in place as opposed to being mobile; also note that **Spillman** discloses that the sensor can detect other parameters, col. 7:47-48) said stent in said pulmonary vein (analogues passageways and arteries disclosed in Walsh col. 4:1-4) proximate the ostium (intended use).

Note: a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is **capable** of performing the intended use, then it meets the claim. (Also note that analogues to a pulmonary vein are disclosed: arteries and passageways in col. 4:1-3. This increases

the likelihood that the Walsh structure is capable of use in the pulmonary vein as the Applicant claims.)

Dependent claims

22. The system according to claim 18, wherein said stent is constructed of an alloy having a shape memory (col. 4:4-6, "nitinol").

23. The system according to claim 18, wherein said stent is constructed of a biodegradable material (col. 4:4-6, "nitinol").

However, in an analogous device/method (see the stent 32 in figure 6a), ***Spillman*** *discloses a sensor (68) for monitoring electrophysiologic cardiac properties (blood pressure, col. 7:32) of said subject for determining if a predefined end point has been reached.*

20. The combination of the two patents suggest predefined end point comprises confirmation of a block of electrical conductivity at said target tissue (intended use language). Also note that an abrupt change in sensed blood pressure (blood pressure, col. 7:32; sensed parameters related to impedance, resistance, capacitance – col. 7:26-34 and col. 7:45-55) in theory could **capably** provide confirmation of a conduction block.

21. The combination of the two patents suggest a plurality of capacitors (C1, C2 in figure 5a in Walsh) in said resonant circuit; and a **control circuit (60 in Spillman figure 3)** for automatically selecting one of said capacitors responsively to a frequency of said electromagnetic field to so as to conform said resonant frequency of said resonant circuit with said frequency of said electromagnetic field.

24. The system according to claim 18, further comprising: a localizing subsystem (60 Spillman) for tracking a position and orientation of said catheter (through sensing with 68, Spillman), comprising: a plurality of localizing field generators (65) disposed external to said subject; a position (68) sensor on said catheter that is responsive to localizing electromagnetic fields produced by said localizing field generators; and a receiver (65) responsive to an output of said position sensor.

The motivation to combine the patents is to monitor the condition of the implant/stent as allowed by the Spillman stent depicted in figure 6a and is found in Spillman col. 1:22-24.

Therefore, at the time of the invention in would have been obvious to one of ordinary skill in the art to modify Walsh in view of Spillman by including feedback and position sensors. Again, the motivation to combine the patents is to monitor the condition of the implant/stent and is found in Spillman col. 1:22-24.

25. The system according to claim 18 wherein said stent (10) and said resonant circuit (18) form a body in the shape of a ring oriented in a plane extending radially of the axis of the pulmonary vein (intended use). This is depicted in Walsh figure 8. (46 is a vessel, which includes by definition the pulmonary vein.)

26. The system according to claim 25 wherein said ring comprises a capacitor core (22) and an inductor coil (14) wound around said capacitor core (22).

27. The system according to claim 26 wherein said capacitor core has a slit. A slit is arguably an obvious design choice that if beneficial would be determined through routine experimentation. The Applicant has neither described the slit **in the original disclosure** nor provided any criticality **in the original disclosure** to the presence of the slit.

28. The system according to claim 25 wherein said stent is positioned in facing relative to the ostium of the pulmonary vein. *This is intended use language.*

29. The system according to claim 28 wherein the position of the stent relative to said ostium is such that the target tissue is ablated near said ostium to block electrical conductivity of said tissue and thereby counteract arrhythmia in the heart chamber. *This is intended use language.*

Response to Arguments

Applicant's arguments filed 6-13-06 have been fully considered but they are not persuasive. Spillman has sensors now seen in independent claim 18.

Note that Walsh et al. refers to stent implantation in "vessel[s]" in figure 7 and col. 4:2, "arter[ies]" in col 4:2 and "passageway[s]" in col. 4:2. This certainly makes obvious use of the stent in the pulmonary vein (certainly a passageway/vessel, and analogous to an artery) the Applicant is claiming in **system** claims 18-29.

Further, claim language toward use in the pulmonary vein is intended use. If the prior art is **capable** of use in the pulmonary vein, then it anticipates or makes obvious the claim. The fact that Walsh discloses a stent for use in arteries and passageways increases the likelihood that the Walsh structure is capable of use in the pulmonary vein as the Applicant claims.

The Office understands that the Applicant's purpose is different from the prior art. However, the structures found in the prior art make obvious the Applicant's claims notwithstanding the differences in purpose. The Office cannot rely upon generalized arguments such as "the construction of the claimed system is *uniquely adapted* for this purpose" to obviate the rejections. Further, different dimensions between the prior art and claims (to permit different purposes) are not sufficient to obviate rejections. MPEP § 2144.04 IV A.B. elaborates on this point. This also addresses the obvious difference between a ring (Applicant) and a solenoid (prior art), which are both cylinders of different lengths.

The Applicant questions the combination of Spillman and Walsh (the presented prior art). Walsh discloses a **stent** with a resonant circuit. Walsh is silent however toward sensors and control. Spillman, in an analogous **stent** (col. 1:14) provides sensors and control. Spillman also discloses the motivation to include monitoring through sensors for **stents** in col. 1:22-24 thereby providing the rationale to combine Spillman's sensors with the Walsh stent. The fact that pulmonary vein electroconductive blockage is not mentioned in the prior art is patentably irrelevant as the claims are toward a system, and as such structural equivalence (as discussed above) between the prior art and the Applicant's claims is what is the governing factor.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
August 30, 2006

ROY D. GIBSON
PRIMARY EXAMINER